Adverse Drug Reaction (ADR) Reporting Form

A. Patient Details

Patient initials:	Date Of Birth:
☐ Male ☐ Female (☐ Pregnant ☐ Not Pregnant)	Wight: Hight:

B. Suspected Drug/s

Drug\s Name (including generic name\s)	Manufacturer & Bach Number	Dose Route of Administration	Dose Frequency	Start Date	End Date	Indication (purpose of use)

C. Concomitant Drug (Exclude those used to treat the reaction)

Drug\s Name (including generic name\s)	Manufacturer & Bach Number	Dose Route of Administration	Dose Frequency	Start Date	End Date	Indication (purpose of use)

D. Adverse Drug Reaction Description	
Adverse event including relevant test/lab data & Dates	Other relevant history, including pre-existing medical conditions; (Diagnosis, allergies, pregnancy, hepatic, renal etc. …)
Date when event started:	Date when event disappeared (if applicable):

E. Action Taken					
☐Drug discontinued	☐Dose reduced	☐Dose increased	☐Dose not changed	☐Unknown	☐Not applicable

F. Outcome of ADR				
☐The patient recovered date	☐Recovering	☐No improvement	☐Died	☐Unknown
Event subsided after stopping the suspected drug (DE challenge)		☐No	☐Yes	☐Unknown
Event subsided after reintroducing the suspected drug (Rechallenge)		☐No	☐Yes	☐Unknown
Specific antagonist used		☐No	☐Yes	☐Unknown

G. Seriousness of ADR		
☐Patient died date	☐Hospitalization	☐Life threatening
☐Congenital anomaly	☐Permanent disability	☐Prolonged the hospitalization (above 24 hr.)
☐Require emergency room (visit)	☐Required intervention to prevent permeant impairment\damage	
☐None of the above		
Comments:		

H. Reporters Details		
Reporter name:		Specialty / Profession:
Center:		Address:
Mobile / Phone:		E-mail:
Fax:	Date:	Signature:

Adverse Dug Reaction (ADR) is a response to medicinal product which is noxious and unintended. Response in this context means that the causal relationship between a medicinal product & adverse event is at least a reasonable possibility

Serious adverse reaction happened when one or more of these observed:

- Patient death
- Life threatening
- Require hospitalization or prolongation of existing hospitalization
- Result in significant or persistent disability
- Congenital anomaly / birth defect

This form can be filled by:	How to report:
➢ Doctors ➢ Dentists ➢ Pharmacists ➢ Nurses ➢ Other healthcare provider	➢ Fill out the reporting form ➢ Attach additional information (if it is available) *USE A SEPARATE FORM FOR EACH ADR **Submit the form's to:** • Unicare for pharmaceutical industries Riyadh-Saudi Arabia, Second Ind. Area, Exist 16 Street No.6 • E-mail: Info@unicare-pharma.com.sa • Phone: +966 11 2330677 ext. 2.